

14. THERMOMETER (DATA LOGGER) POLICY

Montana VFC Thermometer Requirements

The CDC and the Montana Immunization Program require thermometers in all VFC vaccine storage units to meet the following requirements:

- Certified calibrated/tested as accurate against NIST or ASTM measurement standards annually or within the timeframe recommended by the **manufacturer evidenced by a current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report.**
- Continuously monitoring by measuring and permanently recording temperatures on a predetermined schedule so that the data can be reviewed and permanently archived for three years.
- Capable of recording and saving temperature readings at a minimum of every 15 minutes.
- Uses a thermocouple probe in a glycol or glass bead buffer medium
- Capable of displaying current temperature and minimum/maximum temperatures without having to open the storage unit door
- **Has an out-of-range temperature alarm with thresholds set at proper vaccine storage temperatures.**

State-Supplied Thermometers – Data Loggers

The Montana Immunization Program provides program-compliant digital Data Loggers to all VFC providers in Montana. Data Loggers are electronic thermometers that continuously record and store current and min/max temperature readings and indicate through a warning light when out-of-range temperatures have been encountered. Data Loggers interface with a computer so that data can be removed, reviewed, and saved.

Immunization Program Responsibilities

- The Immunization Program supplies Data Loggers free-of-charge to VFC providers in the state. Each Data Logger comes with:
 - Instrument Calibration Report
 - Data logger cradle and attachment kit for mounting on outside of storage unit
 - Thermocouple probe housed in a glycol-containing bottle and connected to the Data Logger by a 4-foot wire. Acrylic stand for the glycol bottle
 - Extra battery
 - Software for controlling the unit and saving data
 - Montana VFC Program Data Logger Instruction Manual
- **If a provider chooses to supply their own program-compliant thermometers, they must meet the requirements as defined above. The Immunization Program must approve provider-supplied thermometers and issue a memo exempting the provider from using a State-supplied Data Logger. To obtain thermometer approval, providers must submit to the Immunization Program:**
 - One week of temperature recordings
 - Thermometer product specifications

- **Current Certificate of Traceability and Calibration Testing, Report of Calibration Testing, or Instrument Calibration Report that meets CDC requirements.**
- The Montana Immunization Program and the Data Logger supplier provides training, technical support, and written instructions for using the Data Loggers.
- The Montana Immunization Program facilitates a recalibration program for State-supplied Data Loggers at the provider's expense (terms of recalibration may change year to year).
- **The Immunization Program reviews Data Logger data and approves storage units/thermometers for:**
 - **New VFC providers**
 - **Providers setting up a new VFC storage unit**
 - **Providers reinstating a VFC storage unit after a repair**
 - **Providers commissioning a new Data Logger or other program-compliant thermometer.**

Provider Responsibilities

- All VFC providers are required to use the State-supplied Data Loggers in each VFC vaccine storage unit unless they have an Immunization Program-approved thermometer that meets the VFC requirements as defined above.
- If using State-supplied Data Loggers, providers must have a Windows®-based computer for running the Data Logger software and a storage location for the Data Logger data.
- **VFC providers must have all VFC vaccine storage units/thermometers approved for use by following the instructions on page 50 (Storage Unit Approval).**
- Providers are responsible for replacing broken or malfunctioning Data Loggers with an equivalent unit.
- Providers are responsible for Data Logger re-calibration and may use the state-facilitated re-calibration program or a vendor of their choice as long as they offer equivalent services.
- Providers must have an emergency backup thermometer on hand in the event that the Data Logger breaks or malfunctions. Backup thermometers must be working and reliable but are not required to be certified calibrated, continuously monitoring, or have a thermocouple probe in glycol.
- Providers terminated from the VFC Program must return State-supplied Data Loggers to the Immunization Program.

In the routine use of Data Loggers, providers must:

- Prior to first use and after each data download, use the provided software to set up and activate each Data Logger according to Immunization Program guidance.
- **After activation, properly place a Data Logger in each VFC vaccine storage unit.**
- **Manually perform the daily temperature monitoring activities outlined in Section 13, (page 54 – Routine Temperature Monitoring) using the state-supplied data logger or other program-complaint thermometer.**
- At the end of every month (prior to reconciling inventory and ordering vaccine) download, review, and save Data Logger data for the previous month. Save monthly Data Logger data and paper temperature logs for three years.
- Respond to out-of-range temperature indications as outline in Section 13, Out of Range Temperatures.

- Make Data Logger data and temperature logs available for review during VFC site visits from the Montana Immunization Program.

See the *Montana VFC Data Logger Instruction Manual* for specific details on setting up and using your Data Logger. A copy is available on our website at www.immunization.mt.gov under the “VFC” link.